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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,439	10/24/2001	Andrew Saxon	UC067.004A	9201

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EXAMINER	
HUYNH, PHUONG N	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/000,439	SAXON, ANDREW	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/24/01; 12/30/02*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-59* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

I. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

II. Claims 1-59 are pending.

III. IT is noted that the preambles of claims 28-34 recite "the method" rather than the fusion molecule. However, claims 1 and 27 from which claims 28-34 depend from are drawn to an isolated fusion molecule and not method. Therefore, the restriction of claims 28-34 has been set forth as fusion molecule, irrespective of the format of the claims.

Election/Restrictions

IV. Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 2-34, and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **myelin basic protein**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1; Class 435, subclass 810.

2. Claims 2-34, and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **proteolipid**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1; Class 435, subclass 810.

3. Claims 2-34, and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **myelin oligodendrocyte glycoprotein**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1; Class 435, subclass 810.

4. Claims 2-34, and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **αβ-crystallin**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1; Class 435, subclass 810.

5. Claims 2-34, and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **myelin-associated glycoprotein**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1; Class 435, subclass 810.

6. Claims 2-34, and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **Po glycoprotein**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1; Class 435, subclass 810.

7. Claims 2-34, and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **PMP22, 2'3'-cyclinucleotide 3'phosphohydrolase**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1; Class 435, subclass 810.

8. Claims 2-34, and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **glutamic acid decarboxylase (GAD)**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1; Class 435, subclass 810.

9. Claims 2-34, and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **insulin**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1; Class 435, subclass 810.

10. Claims 2-34, and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **64 kD islet cell antigen (IA-2 or ICA512)**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1; Class 435, subclass 810.

11. Claims 2-34, and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **phogrin (IA-2β)** pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1; Class 435, subclass 810.

12. Claims 2-34, and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **type II collagen**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1; Class 435, subclass 810.

13. Claims 2-34, and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **human cartilage gp39 (HCgp39)**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1; Class 435, subclass 810.

14. Claims 2-34, and 40-44, drawn to an isolated fusion molecule wherein the autoantigen is **gp130-RAPS**, pharmaceutical composition and kit comprising said fusion protein, classified in Class 530, subclass 350; Class 424, subclass 192.1; Class 435, subclass 810.

15. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **myelin basic protein**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

16. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **proteolipid**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

17. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **myelin oligodendrocyte glycoprotein**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

18. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **αβ-crystallin**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

19. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **myelin-associated glycoprotein**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

20. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **Po glycoprotein**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

21. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **PMP22, 2'3'-cyclic nucleotide 3'phosphohydroase (NCPase)**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

22. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **glutamic acid decarboxylase (GAD)**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

23. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **insulin**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

24. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **64 kD islet cell antigen (IA-2 or ICA512)**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

25. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **progrin (IA-2β)**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

26. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **type II collagen**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

27. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **human cartilage gp39 (HCgp39)**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

28. Claims 36-39, drawn to an isolated nucleic acid molecule encoding the fusion protein wherein the autoantigen is **gp130-RAPS**, vector, and host cells, classified in Class 536, subclass 23.5; Class 435, subclass 320.1 and 252.

29. Claims 46-50, drawn to a method for treating autoimmune **rheumatoid arthritis** comprising administering an effective amount of at least one specific fusion protein, classified in Class 424, subclass 192.1.

30. Claims 46-50, drawn to a method for treating autoimmune **Type-I diabetes** comprising administering an effective amount of at least one specific fusion protein, classified in Class 424, subclass 192.1.

31. Claims 46-50, drawn to a method for treating autoimmune **Multiple Sclerosis** comprising administering an effective amount of at least one specific fusion protein, classified in Class 424, subclass 192.1.

32. Claims 51-59, drawn to a method for the prevention of symptoms resulting from a type I hypersensitive reaction and a method of prevention of a specific type I hypersensitivity disease in a subject comprising administering a specific fusion molecule, wherein the second polypeptide is an allergen, classified in Class 424, subclass 192.1.

Liking claim 1 will be examined along with claims 7-34 and 40-44 if any one of Groups 1-14 is elected.

Liking claim 35 will be examined along with claims 36-39 if any one of Groups 15-28 is elected.

Liking claim 45 will be examined along with claims 46-50 if any one of Groups 29-31 is elected.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups 1-28 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the products fusion protein and polynucleotide as claimed differs with respect to their structures, and physiochemical properties. Therefore, they are patentably distinct.

Inventions of Groups 29-32 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of treating distinct disease using distinct product as claimed differs with respect to their etiology, treatment steps and therapeutic endpoints. Therefore, they are patentably distinct.

Inventions of Groups 1-28 and Groups (29-32) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products as claimed can be used in treating different disease as claimed or materially different process such as binding assays, and identifying compound. Therefore, they are patentably distinct.

V. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods comprising the distinct method steps. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

VI. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

VII. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

VIII. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.

IX. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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